ISRCTN87343655 https://doi.org/10.1186/ISRCTN87343655

# Open, randomised phase III study assessing the toxicity and efficacy of platinum-based chemotherapy with vitamin supplementation in the treatment of lung cancer

**Submission date**
11/11/2005

**Recruitment status**
No longer recruiting

**Registration date**
24/11/2005

**Overall study status**
Completed

**Last Edited**
03/03/2015

**Condition category**
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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Dr Mary O'Brien

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## Additional identifiers

**Protocol serial number**
N/A

## Study information

**Scientific Title**

Open, randomised phase III study assessing the toxicity and efficacy of platinum-based chemotherapy with vitamin supplementation in the treatment of lung cancer

### Acronym
MVPV1

### Study objectives
To assess whether the addition of vitamin supplementation to chemotherapy may decrease treatment related toxicity and improve efficacy and outcome

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved by the Royal Marsden Hospital, 20/01/2006, ref: 05/Q0801/178

### Study design
Open randomised phase III trial

### Primary study design
Interventional

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Lung cancer

### Interventions
Cisplatin-based chemotherapy +/- vitamin supplementation

### Intervention Type
Mixed

### Primary outcome(s)
1. Incidence of neutropenia
2. Incidence of mucositis
3. Incidence of emesis

### Key secondary outcome(s))
1. Disease response by Response Evaluation Criteria in Solid Tumors (RECIST) criteria
2. Response rate
3. Overall survival

### Completion date
01/01/2008

## Eligibility

### Key inclusion criteria
1. Written informed consent
2. Male or female, aged over 18 years
3. Histologically or cytologically confirmed Non-Small Cell Lung Cancer (NSCLC), SCLC or mesothelioma: locally advanced or metastatic; where giving cisplatin 75 mg/m^2 is appropriate
4. Eastern Cooperative Oncology Group (ECOG): performance status (PS) zero to two
5. Lab requirements at entry: serum creatinine less that or equal to 1.25 Upper Limit of Normal (ULN), creatinine clearance more than 50 ml/min (Ethylene Diamine Tetra-acetic Acid [EDTA]) or more than 60 ml/min (C+G), white blood cell count (WBC) more than 3 x 10^9/l, neutrophils more than 1.5 x 10^9/l, platelets more than 100 x 10^9/l
6. Presence of at least one bi-dimensionally measurable index lesion
7. Effective contraception if indicated
8. Estimated life expectancy of at least 12 weeks
9. Patients are required to stop all complimentary medicines and prior vitamin supplements

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria
1. Pregnant or lactating women
2. Active infection
3. Inability or unwillingness to take vitamin supplementation
4. Serious systemic disorders incompatible with the study at the discretion of the investigator

### Date of first enrolment
01/01/2006

### Date of final enrolment
01/01/2008

## Locations

### Countries of recruitment
United Kingdom

England

**Study participating centre**
**Royal Marsden Hospital**
Sutton
United Kingdom
SM2 5PT

# Sponsor information

**Organisation**
Royal Marsden Hospital (UK)

**ROR**
https://ror.org/034vb5t35

# Funder(s)

**Funder type**
Government

**Funder Name**
Royal Marsden NHS Foundation Trust

# Results and Publications

## Individual participant data (IPD) sharing plan

**IPD sharing plan summary**
Not provided at time of registration

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 11/12/2014 | | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |